MEETING MINUTES OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES MEDICARE COVERAGE ADVISORY COMMITTEE

January 25, 2005

Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, Maryland

Medicare Coverage Advisory Committee

January 25, 2005

Attendees

Ronald M. Davis, M.D. Chairperson

Michelle Atkinson Executive Secretary

Voting Members
Rita F. Redberg, M.D., M.Sc.
Clifford Goodman, Ph.D.
Anne B. Curtis, M.D.
Tracy R. Gordy, M.D.
Paul H. Barrett, Jr.
Tammy L. Born, DO.
Mary W.L. Lee. Pharm.D.
William F. Owen, Jr., M.D.
Mark Slaughter, M.D.

<u>CMS Liaison</u> Steve Phurrough, M.D., M.P.A..

Consumer Representative
Charles J. Queenan, III

<u>Industry Representative</u> Patricia L. Garvey, Ph.D.

Guest Panelists
Christina Biesemeier, M.S., R.D.
William H. Herman, M.D., M.P.H.
Pamela Snider, N.D.

Tuesday January 25, 2005,8:25 a.m.

The Medicare Coverage Advisory Committee met on January 25, 2005, to discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of physician-supervised behavioral interventions for the treatment of patients with symptomatic coronary artery disease.

The meeting began with a reading of the conflict of interest statement and introduction of the Committee.

<u>CMS Presentation of Voting Ouestions</u>. A CMS representative presented the panel with the questions that the panel would be asked to vote upon at the conclusion of this meeting.

<u>Presentation of the Technology Assessment.</u> Dr. Alex Clark presented a summary of the technology assessment performed at the Alberta Heritage Foundation for Medical Research. Following his presentation, panelists were given the opportunity to ask questions.

Scheduled Public Comments. Dr. Dean Ornish addressed the panel concerning his coverage request, presenting information on his clinical and research efforts. Following his presentation, panelists were given the opportunity to ask questions. Fifteen other speakers addressed the panel concerning the interventions being considered. These speakers included researchers and clinicians, representative of a private insurance payer, representatives of two professional organizations, and seven patients who had participated in intensive intervention programs.

<u>Onen Public Comments.</u> Four speakers addressed the panel, including a representative from a private insurance payer, and three researchers and clinicians.

Open Panel Discussion. Following a lunch break, the panel engaged in a general discussion, including extensive questioning of many of the presenters.

Final Remarks and Vote.

Prior to voting on the question, a majority of the panel voted to inform CMS that for purposes of their recommendations, physician-supervised behavioral interventions would be taken to refer to interventions that are comprehensive, intensive and multidisciplinary. Also, there was unanimous consensus of the panel that for purposes of their recommendations, long-term would mean greater than one year, and short-term would mean one year or less.

Question 1. How well does the evidence address the effectiveness of physician-supervised behavioral interventions for patients with symptomatic coronary artery disease as compared to usual medical/surgical management? Panelists voted, with average score for voting members of 3.67, average score for entire panel of 3.71.

Question 2. How confident are you in the validity of scientific data on the following outcomes with respect to physician-supervised behavioral interventions for patients with symptomatic coronary artery disease:

Cardiac event, including angina? Panelists voted, with average score for voting members of 3.78, average score for entire panel of 3.64.

Long-term survival? Panelists voted, with average score for voting members of 3.78, average score for entire panel of 3.93.

Short-term survival? Panelists voted, with average score for voting members of 3.33, average score for entire panel of 3.43.

Quality of life? Panelists voted, with average score for voting members of 3.78, average score for entire panel of 3.64.

Question 3. How likely is it that physician-supervised behavioral interventions for patients with symptomatic coronary artery disease will positively affect the following outcomes when compared to usual medical/surgical management:

Cardiac event, including angina? Panelists voted, with average score for voting members of 3.56, average score for entire panel of 3.57.

Long-term survival? Panelists voted, with average score for voting members of 3.56, average score for entire panel of 3.71.

Short-term survival? Panelists voted, with average score for voting members of 2.67, average score for entire panel of 2.79.

Quality of life? Panelists voted, with average score for voting members of 3.56, average score for entire panel of 3.65.

Question 4. How confident are you that physician-supervised behavioral interventions will produce a clinically important net health benefit in the treatment of patients with symptomatic coronary artery disease? Panelists voted, with average score for voting members of 3.56, average score for entire panel of 3.71.

Question 5. Based on the scientific evidence presented, how likely is it that the results of physician-supervised behavioral interventions for patients with symptomatic coronary artery disease can be generalized to:

The Medicare population (aged 65+)? Panelists voted, with average score for voting members of 3.22, average score for entire panel of 3.50.

Providers (facilities/physicians) in community practice? Panelists voted, with average score for voting members of 2.78, average score for entire panel of 2.86.

Remarks. Following the votes, each voting member and nonvoting panelist was given the opportunity to make a statement summarizing reasons for their votes.

Adjournment. The meeting adjourned at 4:05 p.m.

I certify that I attended the meeting of the Executive Committee on January 25, 2005, and that these minutes accurately reflect what transpired.

/s/

Michelle Atkinson Executive Secretary, MCAC, CMS

I approve the minutes of this meeting as recorded in this summary.

/s/

Ronald M. Davis, M.D. Chairperson